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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/041,815	10/18/2001	Wolfgang Muhlbauer	GLAWE-06599	5359

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EXAMINER

SHARAREH, SHAHNAM J

ART UNIT PAPER NUMBER

1617

DATE MAILED: 06/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/041,815

Applicant(s)

MUHLBAUER ET AL.

Examiner

Shahnam Sharareh

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12 and 14-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12, 14-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Amendment filed on March 18, 2005 has been entered. Claims 12, 14-25 are pending.

Applicant's arguments are addressed under the respective pending prior art rejection.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 12, 14-18, 20-25 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Fues et al US Patent 5,143,730 in view of Clark US Patent 4,847,083.

3. Applicant's arguments have been considered but they are not perusisve, because they are not commensurate with the scope of the pending claims.

4. Applicant argues that Fues does not contain lactic acid. (see Arguments at page 4, 4th – 5th para). Accordingly, Applicant then concludes that since Fues compositions does not contain lactic acid, the combined teachings of the references does not teach every element of the present claims. (see Arguments at page 5, 2nd para.).

5. In response, Examiner first states that the instant claims are not limited to lactic acid. Thus, Applicant's arguments are not commensurate with the scope of the claims. Note that Examiner at page 3, of the previous Office Action stated that the calcium lactate in amounts of up to 20% alone or in combination with the oligomers of lactic acid in amounts of about 20-95% meets the instant limitation of claim 18, which is directed to

"at least one additional substance comprise 10-60% by weight of the claimed composition." Essentially, calcium lactate alone or in combination with the oligomers of Fues meet the instant limitation "additional substance."

6. Second, the last Office Action, merely described Fues's compositions comprise calcium lactate and oligomers of lactic acids. Such moieties are respectively hydrolyzed or degraded to lactate groups or lactic acid. In fact, claims 23-27 of Fues attests to existence of free carboxylic acid encompassing lactic acid. (see col 14, lines 1-10).

7. Third, Fues' compositions are bone waxes and are to be applied on the bone. Examiner has then concluded since Fues' compositions provide or contain some amount of lactic acid, it would thus, stimulate collagen regeneration in the bone because as described in Clark, the secondary reference, lactic acid at the wound site would stimulate formation of collagen. Therefore, all elements of the instant claims are described by the combined teachings of the references.

8. Applicant then argues that Clark teaches away from the instant claims because it states "lactic acid production may become excessive, causing area pH to drop to a very low level, thus causing damage to surrounding cells." (see Arguments at page 5 3rd para.) In response, Examiner that Clark's teachings are not a direct teaching away from the instant claims, because possible excessive production of lactic acid is not relevant to the teachings of Fues and the instant claims. Thus, Applicant's conclusion is not correct.

9. Further, Applicant appears to misinterpret what it means to "teach away" from a patented invention. "In general, a reference will teach away if it suggests that the line of

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development flowing from the reference's disclosure is unlikely to be productive of the results sought by the applicant." *In re Gurley*, 31 USPQ2d 1130, 1131-2 (Fed. Cir. 1994). Here, the mere fact that there is a possibility of cell damage if excessive lactic acid is produced does not preclude optimization the use of Fues and the stimulation of collagen regeneration.

10. Specifically, the portions of Clark that Applicant characterizes as a "teaching away" (col 2, lines 46-53) does not discourage one of ordinary skill in the art to employ the teachings of Fues. Further, Applicant has not provided any evidence or explain that the composition of Fues when placed in bone does not create any degree of lactic acid, and/or such amount of lactic acid would not stimulate collagen regeneration within the scope of the instant claims. Therefore, Examiner concludes that a person of one ordinary skill, upon reading the Fues and Clark, would not have been discouraged from expecting to observe stimulation of collagen regeneration.

11. Claim 19 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Fues et al US Patent 5,143,730 in view of Clark US Patent 4,847,083 as applied to claims 12, 14-18 and 20-25 and further in view of Thiele US Patent 3,805,776.

Applicant's arguments are considered but are not found persuasive. Applicant argues that Fues and Clark are not combinable. (see Arguments at page 6). For the reasons set forth in para 3-8, *supra*, the teachings of Fues and Clark are combinable. Thus, the rejection is proper for the reasons of record.

Conclusion

No claims are allowed. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SS

A handwritten signature in black ink, appearing to read 'S. Padmanabhan', with a horizontal line underneath the name.

**SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER**